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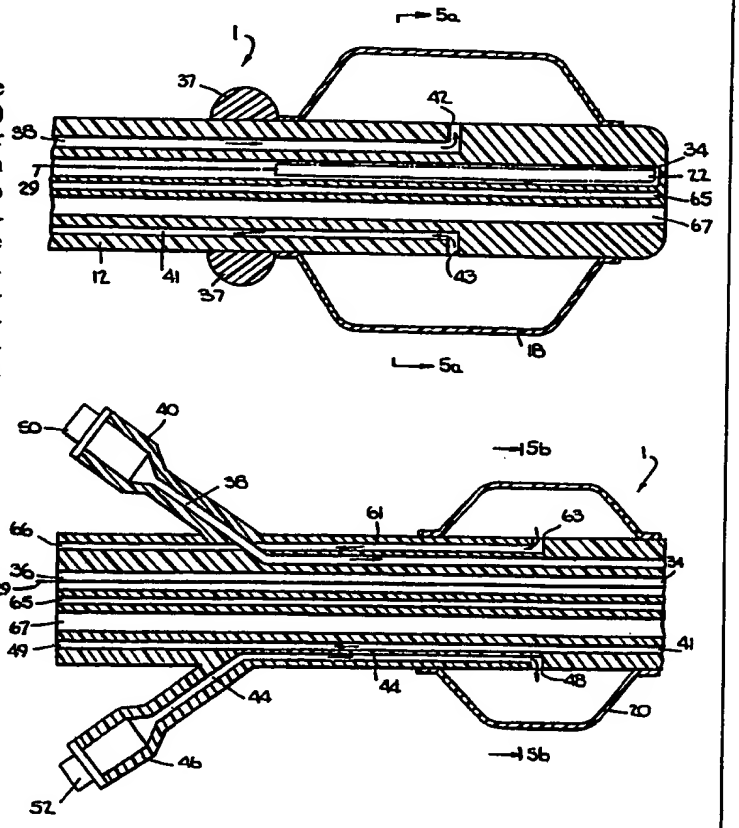
(54) Title: COMBINED HYPERTHERMIA AND DILATION CATHETER

(57) Abstract

An apparatus for treatment of diseases of the prostate, such as benign prostatic hypertrophy (BPH) and prostatic cancer, includes a urinary catheter (1) for insertion in the prostatic urethra; a dilation balloon (18) for simultaneously dilating the prostatic urethra to relieve any constriction of the prostatic urethra generally symptomatic of most diseases of the prostate and for compressing prostatic tissue to restrict blood flow to said tissue, thereby reducing the heat sink effect of blood-supplied tissue absorbing heat energy applied thereto; consequently enabling both greater uniformity of heating in selected target diseased prostatic tissue and a reduction in the amount of power required to supply an effective level of energy to the selected target diseased prostatic tissue; and a microwave antenna (22) for applying microwave energy to the selected target diseased prostatic tissue to produce hyperthermal effects therein, thereby causing therapeutic alteration of the selected target diseased prostatic tissue cells. A method for the treatment of diseases of the prostate utilizing the apparatus is also disclosed.



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COMBINED HYPERTHERMIA AND DILATION CATHETER

Background of the Invention

This invention relates to an apparatus and method for the treatment of diseases of the prostate, including benign prostatic hypertrophy (BPH) and prostatic cancer. In particular, the invention relates to a catheter featuring the combined use of balloon dilation and hyperthermia.

Prostatic disease is one of the most common diseases in men in the United States. Prostatic disease, as referred to here, includes benign prostatic hypertrophy (BPH) and prostatic cancer. These two etiologies affect a majority of men over the age of 60.

The clinical symptoms of BPH include urinary tract outlet obstruction due to an enlarged prostate. The etiology of BPH, while not fully understood, has focused on two hypotheses. The first hypothesis has identified the hyperplastic cell morphology as a stromal cell disease. The second hypothesis has investigated the effects of prohormone dihydrotestosterone (DHT), which is the primary mediator of androgen action in the prostatic cells.

The currently accepted treatment for BPH is transurethral resection of the prostrate (TURP). Approximately 400,000 TURPs per year are performed to treat this disorder in the United States. Morbidity and mortality for TURP are 17 and 1 percent, respectively, for all age groups. Higher complication rates occur in older populations with an annual surgical and hospitalization cost in excess of $1 billion pear year.

Thus, TURP may only be applicable to patients who are not at risk for surgical complications. Among other treatment available for the condition of BPH are pharmacological means such as vasoactive and antiandrogen agents. The vasoactive drugs primarily used are alpha$_1$ receptors which reduce smooth muscle tone within the prostate which is in part responsible for the mechanical obstruction of urine through the prostatic urethra. Although vasoactive drugs have exhibited some efficacy in

relieving symptoms, it should be noted that mechanical obstruction may still exist and may promote the development of urinary tract infection, bladder stones and possible upper urinary tract obstruction.

Antiandrogen agents have also been used to reduce the symptoms associated with BPH. The primary function of these androgen blockers is to reduce the effects of DHT activity in the prostate by competing for the androgen receptors. While there has been evidence of the clinical efficacy of these agents in reducing the size of the prostate and relieving the symptoms associated, the problem with this pharmacological intervention has been the slow onset of therapeutic action for the patient.

With regard to prostatic cancer, both the incidence and mortality are on the rise. It is expected that over 100,000 new cases will be diagnosed this year alone, with some 30,000 cases proving fatal.

While the etiology of prostatic cancer is also not well known, it has been suggested that this disease is either biochemically or genetically induced. The symptoms of prostatic cancer are often insidious and may not be clinically manifest until the course of the disease is advanced. The current treatment of choice for prostatic cancer is to perform a radical prostatectomy which involves surgical excision of the prostate gland.

The use of dilation and hyperthermia has been suggested for treatment of obstructive atheromatous plaque in cardiovascular disease. The etiology of cardiovascular disease is, however, markedly different from that of prostatic diseases.

In cardiovascular disease the source of the obstruction of the lumen is internal to the lumen itself, namely, the deposits of atheromatous plaque on the wall of the vessel. The objective of the apparatus and methods used in the treatment of cardiovascular disease is to widen the lumen of a vessel by compressing and removing the internally obstructive material. The nature of the

obstructive material is markedly different from the living arterial wall tissue and surrounding tissue. It is important in the treatment of obstructive cardiovascular disease that the obstruction in the lumen of the vessel be removed or reduced without causing damage to the tissue of the vessel and surrounding tissue.

U.S. Patent No. 4,643,186 to Rosen et al. for Percutaneous Transluminal Microwave Catheter Angioplasty, and West German Laid-Open Patent Application No. DE 3743578 A1 to Zeiher for Balloon Catheter for Recanalization of Stenoses in Body Channels, in Particular Coronary Vessels and Peripheral and Arterial Vessels, disclose catheters each having at least one embodiment thereof featuring balloon dilation to mechanically compress plaque deposits on the inner surface of a vessel wall to expand the lumen of the vessel, and the application of microwave energy to the plaque to soften, coagulate, and/or electroabrade the plaque, to further expand the effective cross-sectional area of the lumen of the vessel available for flow through the vessel.

U.S. Patent No. 4,799,479 to Spears for Method and Apparatus for Angioplasty, discloses a device utilizing balloon dilation and the application of thermal energy supplied by means of a laser. Balloon inflation is used to facilitate fusion of disrupted plaque, which, together with arterial wall tissue, is heated and fused together to form a smooth, cylindrically-shaped channel in the lumen of the vessel which is resistant to restenosis.

Diseases of the prostate are, in contrast to the aforedescribed cardiovascular conditions, accompanied by a different set of circumstances. The cause of the reduction of the available flow channel in the lumen of the vessel i.e., the prostatic urethra, is an externally induced compression of the vessel wall due to the proliferation of epithelial and stromal cell tissue, which is benign in the case of BPH and cancerous in cases of prostatic cancer. In order to be effective, treatment of diseases of the

prostate must cause a reduction in the mass of the prostatic tissue responsible for creating the compressive forces on the urethra which results in the obstruction of flow through the lumen of the urethra. This is accomplished either by surgical excision of the tissue or by other means which will cause changes in the cells with therapeutic effects.

The use of dilation alone has been known in the art of treatment of BPH. U.S. Patent Nos. 4,932,956 and 4,932,958 both to Reddy et al., both for Prostate Balloon Dilator, and both assigned to the assignee of the present invention, disclose catheters which utilize balloon dilation to expand the lumen of the prostatic urethra. These two patents are incorporated herein by reference.

The use of hyperthermia in the treatment of various forms of cancer, including prostatic cancer, has been attempted for some time. However, this therapy has met with only limited effectiveness due to the fact that blood flow to the target cells is not reduced and may, in fact, increase. Because of blood flow, a heat sink phenomenon occurs which reduces the thermal energy delivered to the target cells, thus reducing the magnitude and uniformity of heating and cell destruction.

In order for hyperthermia to be effective, the temperature of all the target cells must be raised to a minimum of 42.5°C and maintained at that temperature for a sufficient period of time to cause cell changes. Moreover, it has been observed that with small increases in temperature above this minimum level there is an exponential increase in cell changes and concomitant therapeutic effect.

Hyperthermia is also a means for treatment of other, non-cancerous, hyperplastic cell conditions such as BPH.

There is a need in the field of treatment of prostatic disease, both benign and cancerous, for an effective alternative means of treatment to the more radical, and consequently more complicated and more dangerous surgical

procedures which currently are the treatments of choice, namely, TURP for BPH and radical prostatectomy for prostatic cancer.

It is desirable to have an alternative method of treatment and apparatus therefor that is readily adaptable to use in the treatment of either condition.

Heretofore, an apparatus and method of treatment for both benign and cancerous forms of prostate disease that combines the use of dilation and hyperthermia has not been known in the art.

It is an objective of the present invention to fill this need in the art of treatment of prostate disease with an apparatus that combines the use of dilation and hyperthermia and a method for its use in the treatment of both benign and cancerous forms of prostate disease.

Summary of the Invention

Accordingly, the present invention provides an apparatus and method for treatment of prostate disease, both benign and cancerous, which utilizes in combination dilation of the prostatic urethra and the application of hyperthermal effects in diseased tissue cells.

With respect to the treatment of prostate disease, the apparatus and method of the present invention affords dual modes of therapy. For the treatment of BPH in particular, both dilation and hyperthermia have a direct effect in alleviating the symptoms of the disease. For the treatment of prostatic cancer, the contribution of the effects of dilation alone are not fully understood, and will not be markedly evident in alleviating symptoms unless the course of the disease has progressed to the extent that the proliferation of cancerous prostatic cells is large enough to exert a compressing force on the prostatic urethra causing an acute obstruction of the prostatic urethra. In the treatment of all forms of prostatic disease however, the dilation mode of therapy also enhances the efficacy of the hyperthermal mode of treatment by restricting blood to the target tissue thereby reducing the heat sink effect and

allowing the transfer of heat energy to be more readily and uniformly absorbed by the target tissue to produce hyperthermal effects therein.

The heat sink effect is an effect wherein blood-supplied tissue, both healthy and diseased, tends to absorb heat energy in order to dissipate the heat and prevent damage to the tissue. The effect is the result of the high heat capacity of blood. As a natural body safety mechanism to protect healthy tissue, the effect is important to maintaining viability of the tissue and is desirable. In the case of treatment of diseased tissue, which is being hyperthermally treated to destroy the diseased cells, however, the effect is undesirable because both blood-supplied target diseased tissue being treated as well as surrounding blood-supplied healthy tissue tend to dissipate the heat energy intended to be applied to the selected target diseased tissue, thereby requiring the application of increasingly greater power levels to supply an effective level of energy to the target diseased tissue to produce hyperthermal effects therein and achieve a therapeutic result of altering the target diseased tissue cells. This heat sink effect is greatly reduced when blood flow to both the target diseased tissue and the surrounding healthy tissue is temporarily reduced or cut off, because the heat absorbing capacity of tissue unsupplied with blood is significantly reduced. The reduction or cut-off of the blood supply to the tissue is done for a sufficiently long period of time to enable treatment of the diseased tissue, however the blood supply is resumed before necrosis of the healthy tissue occurs. The temporary application of pressure to the tissue is sufficient to cause a reduction in blood flow to the tissue. In the treatment of diseases of the prostate with the apparatus of the present invention, this is conveniently achieved utilizing the dilation balloon, which when inflated to proper pressure, both dilates an obstructed prostatic urethra and also causes a reduction in blood flow to all tissue being

compressed, both the target diseased prostatic tissue as well as surrounding healthy prostatic and urethral tissue and tissue of the urethelium, the lining between the prostate and the urethra. This enables a more effective hyperthermal treatment of diseased tissue utilizing minimum power consumption.

The apparatus of the present invention comprises a flexible catheter tube for insertion into the urethra. Mounted on the catheter tube at the distal end thereof, are dilation means for dilating the prostatic urethra and heating means for transmitting energy to surrounding prostatic tissue to cause hyperthermal effects therein and subsequent alteration of the tissue cells. In a preferred embodiment of the apparatus, the dilation means is a dilation balloon and the heating means is a microwave antenna.

Other alternative embodiments of the apparatus incorporate one or more additional features including a fixation balloon for securing the apparatus in place after it has been anatomically correctly positioned; cooling means for temperature moderation of the heating means to prevent overheating and for cooling the urothelium adjacent to the prostatic urethra to prevent damage to the tissue of the urothelium; a guidewire to facilitate insertion of the apparatus and increase its stiffness; a protuberance on the catheter tube, capable of being rectally palpated by the physician to assist in positioning of the apparatus; temperature sensing means for monitoring the temperature of the heating means; and feedback circuit means for regulating the amount of energy provided by the heating means.

Brief Description of the Drawings

Fig. 1 shows a combined dilation balloon and hyperthermia catheter according to the present invention.

Fig. 2 shows a combined dilation balloon and hyperthermia catheter according to the present invention, also incorporating a fixation balloon, as it is inserted

in the male urethra with both fixation balloon and dilation balloon in inflated condition.

Fig. 3 is a fragmentary sectional view of the apparatus of Fig. 2.

Fig. 4a is a cross-sectional view of the distal end of the device of Fig. 3 showing the dilation balloon in inflated condition.

Fig. 4b is a cross-sectional view of the proximal end of the device of Fig. 3 showing the fixation balloon in inflated condition.

Fig. 5a is a cross-sectional end view of the apparatus through location 5a-5a of Fig. 4a.

Fig. 5b is a cross-sectional end view of the apparatus through location 5b-5b of Fig. 4b.

Fig. 6 shows details of a microwave antenna as typically utilized in the apparatus of the present invention.

Detailed Description of the Invention

As used hereinafter, the term proximal refers to an orientation towards the end of the apparatus external to the urethra and nearest the operator of the apparatus and distal refers to an orientation towards the end of the apparatus which is inserted into the urethra, nearest to the bladder.

Referring to Fig. 1, a combined dilation balloon and hyperthermia apparatus 1 according to the present invention is illustrated, showing a dilation balloon 18 in deflated position for insertion and withdrawal and in inflated position (shown in dashed lines) for dilation of the prostatic urethra. Heating element 22 at the distal end of the catheter tube 12 is also shown.

Referring to Fig. 2, a combined dilation balloon and hyperthermia apparatus 1, also including a fixation balloon 20, according to the present invention is illustrated, positioned within the male urethra 11. Inflatable fixation balloon 20 is mounted on catheter tube 12 a distance from the distal end thereof such that when the apparatus 1 is

properly positioned, fixation balloon 20 is located within the bulbous urethra, distal to the external sphincter 21. In order to avoid damaging the external sphincter by dilation, protuberance 37 is circumferentially located on catheter tube 12 at a position between fixation balloon 20 and dilation balloon 18 in a direction towards the proximal end of catheter tube 12 to facilitate correct positioning of the apparatus 1 through rectal palpation of the protuberance 37 by the physician. The fixation balloon 20 anchors the apparatus 1 in place and secures it against significant movement in the longitudinal direction, particularly, past the bladder neck 17 and up into the bladder. Inflatable dilation balloon 18 is mounted on catheter tube 12 at its distal end and when the apparatus 1 is in place, is properly positioned in the prostatic urethra 9 which passes through the prostate 15. Heating means 22 is axially mounted at the distal end of catheter tube 12 and is situated inside dilation balloon 18. The heating means is a microwave or radio frequency transmitting antenna or a heat-conducting element through which a thermal fluid is circulated to provide heat. In a preferred embodiment of the apparatus, the heating element 22 is a microwave antenna which radiates microwave energy at a frequency of about 915 MHz.

Catheter tube 12 is formed of a material which is sufficiently flexible to follow the shape of the urethra upon insertion of the apparatus, while also being sufficiently rigid to enable the apparatus to pass any obstructions in the urethra without bending. Catheter tube 12 is composed of or is covered with a biocompatible material to avoid irritation of the urethra. Suitable materials for catheter tube 12 include silicone, polyester, polyvinylchloride and polyurethane.

In one alternative embodiment of the apparatus, dilation balloon 18 is replaced with a plurality of smaller dilation balloons which can be inflated either separately

or together and which give the distal end of the apparatus greater flexibility.

Where the dilating force exerted by the inflated dilation balloon is insufficient to overcome the curvature of the prostatic urethra, the energy field radiated by the heating element 22 may be asymmetrical.

Therefore, in one alternative embodiment, a plurality of centering balloons are positioned inside dilation balloon 18 to maintain heating element 22 equidistant from the surface of the dilation balloon. This helps to ensure that the amount of energy reaching prostatic tissue is uniform and symmetrical.

Dilation balloon 18 is formed of a biocompatible material such as silicone elastomer, polyvinylchloride, polyester, polyethylene terephthalate, polyurethane, or natural or synthetic rubber. The dilation balloon 18 is fabricated such that it does not expand beyond a predetermined diameter. The limited expendability of dilation balloon 18 prevents over-dilation and possible damage to the prostatic urethra during dilation. The limited expandability of the dilation balloon 18 is achieved in one embodiment by fabricating the balloon of a nondistensible material selected from the above-mentioned biocompatible materials, namely, polyvinylchloride, polyethylene terephthalate and polyethylene. In the deflated state, such a balloon made from a non-distensible material is in a folded configuration. Alternatively, limited expandability of dilation balloon 18 is achieved by making the balloon of a limited distensible composite material wherein an elastic balloon material is surrounded by a non-elastic material, such as cloth, which limits the expansion size of the balloon and assists in deflation of the balloon. Typically, the dilation balloon 18 is expandable to a diameter of from about 40 French to about 120 French, where the diameter in French is 3.0 times the diameter in millimeters (mm). Therefore, the dilation

balloon 18 of the present apparatus ranges in size from about 12 to about 40 mm in diameter.

Hyperthermia is induced in the target cells by the application of energy to the cells to cause a temperature rise to a therapeutic temperature of at least 42.5°C for a sufficient time to cause therapeutic changes in the target cells. The energy supplied to the tissue cells can be in any form that will effect heating of the tissue. Typically, the energy is electromagnetic radiation energy in the microwave or radio frequency (RF) range, or is thermal conductive energy supplied by circulation of a hot fluid, such as hot water, in the distal end of the apparatus. Microwave energy is the preferred form. Depending on the type of energy utilized, the antenna 22 located at the distal end of the apparatus inside the catheter tube 12 and dilation balloon 18 is suitably designed to radiate electromagnetic energy.

Microwave antenna 22 is typically a linear coaxial microwave antenna with choke or a standard single junction dipole microwave antenna. The latter is depicted in Fig. 6. The dipole microwave antenna 22 is constructed from a semi-rigid coaxial cable having an inner conductor 52 covered by an insulator 53. The microwave antenna 22 is mounted in antenna lumen 34. The coaxial cable 29 from which the antenna is formed extends from the proximal antenna opening 36 through the length of catheter tube 12 and terminates in the slotted radiating portion of the antenna 22 at the distal end of antenna lumen 34 in catheter tube 12.

In alternative embodiments of the apparatus, the antenna is fixedly attached, slidably mounted or detachably mounted in the antenna lumen 34. The antenna is generally fixed when the overall apparatus is manufactured to be disposable. The antenna is typically slidably mounted where the antenna is of the single junction type with one radiating gap or slot to enable movement of the antenna to direct maximal radiated energy onto various portions of the

prostatic tissue along the prostatic urethra. The antenna is detachable where use of a more expensive type of antenna is contemplated and only the catheter tube portion of the apparatus is disposed of after use.

For a single junction dipole antenna 22, an outer conductor 54 is cut circumferentially from the coaxial cable at location 55 to form an axial separation gap of about 0.1 cm between the cut portions of the outer insulator. A metallic connector 56 is soldered between the distal ends of the inner and outer conductors. This simple dipole type antenna operates substantially identically to other dipole style antennae having a soldered connection between the inner conductor and the outer conductor adjacent to the gap. The operation of the dipole microwave antenna 22 as is utilized in the apparatus of the present invention is described more fully in U.S. Patent No. 4,825,880 to Stauffer et al for Implantable Helical Coil Microwave Antenna, which is incorporated herein by reference. Other types of dipole antennae, such as the sheered coaxial slot type, the balun-fed folded dipole type, the multiple junction type, the bare-tip type, and the insulated-tip type as are known in the art, may alternatively be utilized as the microwave antenna 22 in other embodiments of the apparatus of the present invention.

In one alternative embodiment of the apparatus, utilizing a single junction dipole antenna which is characterized by producing a narrow, mono-nodal peak energy pattern, and due to geometrical considerations in treating an elongated enlarged prostate, the microwave antenna 22 is slidably mounted inside the antenna lumen 34. The apparatus may then be operated in such a way as to enable the antenna 22 to be moved forward and backward within the catheter tube 12 during the catheterization procedure to uniformly expose the prostatic tissue to the maximum amount of energy radiated from a single junction dipole antenna.

In this procedure, the position of the antenna can be monitored by ultrasound imaging or by X-ray fluoroscopy.

In alternative embodiments of the apparatus, catheter tube 12 has a plurality of from 2 to 6 lumens for various features.

Figs. 5a and 5b are cross-sectional views of the apparatus 1 at locations 5a-5a and 5b-5b, respectively, of the catheter tube 12, as shown in Figs. 4a and 4b.

Referring to Figs. 4a, 4b, 5a, and 5b, antenna lumen 34 extends from the distal end of catheter tube 12 through the tube to the proximal end where it terminates in proximal antenna opening 36. Dilation lumen 38 communicates between dilation balloon inflation port 40 and dilation balloon 18, via dilation balloon opening 42. Figs. 4a, 4b, 5a and 5b additionally show other lumens in a preferred embodiment of the apparatus. Fixation lumen 44 communicates between fixation balloon inflation port 46 and fixation balloon 20 via fixation balloon opening 48.

One alternative embodiment of the apparatus includes a plurality of more than two ports and connectors for other lumina, such as for the inflation cooling outflow, thermometry means,and antenna. The ports may be arranged in a manifold. Dilation balloon inflation port 40 and fixation balloon inflation port 46 are each provided with a valve or a syringe fitting 50 and 52, respectively, to allow for connection of the fill ports with syringes or other means for injection or circulation of inflation/cooling fluid. Dilation drainage lumen 41 communicates between dilation balloon 18, via dilation balloon outlet 43 to dilation outlet port 49. Fixation drainage lumen 61 communicates between fixation balloon 20, via fixation balloon outlet 63 to fixation outlet port 66. In an alternative embodiment, where the inflation/cooling fluid circulated in both the fixation balloon 20 and the dilation balloon 18 is the same, dilation lumen 38 and fixation lumen 44, and dilation drainage lumen 41 and

fixation drainage lumen 61, are combinable into single inflation and drainage lumens, respectively.

Thermometry lumen 65 accommodates thermometry means used to monitor the temperature of the surface of microwave antenna 22. This lumen also extends the full length of catheter tube 12. A temperature sensor is in communication with the microwave antenna surface at the distal end of the apparatus.

The apparatus may also include a feedback circuit for regulating the amount of energy provided to the antenna 22.

Urine drainage lumen 67 allows urine to drain from the bladder 17 while the apparatus is in position. Urine drainage lumen 67 extends from the distal end of the catheter tube 12, which is positioned in the bladder neck, all the way through to the proximal end of the catheter tube.

In one embodiment of the apparatus, the fixation and dilation balloons are capable of being inflated to a predetermined size by the injection of corresponding volumes of inflation fluid into each, which is supplied through their respective inflation lumens or through a common inflation lumen in the case where the apparatus is so adapted to utilize a single common inflation fluid supplied through a single lumen. The corresponding drainage lumen or lumens are closed by closing the respective outlet port(s) and the fluid is injected to inflate the balloons. The inlet port(s) are then closed to maintain the fluid inside the balloons.

In a preferred alternative embodiment of the apparatus, a cooling fluid or fluids, which are identical to the inflation fluid or fluids utilized to inflate the fixation and dilation balloons are dynamically circulated through the inflation lumen(s), into the balloons and out through the drainage lumen(s). There is a holdup volume of fluid in each of the balloons during the circulation to maintain them in inflated condition during the procedure. For this embodiment, there is either a continuous supply of

fluid or a closed loop system with external cooling and recirculation. The inflation/cooling fluid circulated through the dilation balloon is in contact with microwave antenna 22 and serves to moderate the antenna surface temperature to prevent overheating. This also allows more efficient absorption of the energy being radiated from the antenna by the diseased tissue being hyperthermally treated. The circulated inflation/cooling fluid also functions to cool the surface of the dilation balloon which is in contact with the urothelium 23 and thereby prevents the temperature of the tissue of the urothelium from rising to a level where changes to the healthy tissue of the urothelium in proximity to the target cells can occur.

The flow rate of the fluid being circulated and the capacity of the lumens conducting the flow is determined by the amount of cooling required to moderate the antenna surface temperature and maintain the surface temperature of the urothelium below the therapeutic temperature at which tissue damage and cell destruction occur.

A method of use of the apparatus in the treatment of diseases of the prostate is now described.

Before insertion into the urethra 11, the apparatus 1 is in a first state wherein dilation balloon 18 and fixation balloon 20 are completely deflated and collapsed against the exterior of catheter tube 12. Microwave antenna 22 is axially mounted within the entire length of the distal end of catheter tube 12 and is surrounded by deflated dilation balloon 18.

The apparatus 1 is guided into and along the urethra. To facilitate insertion, the apparatus 1 may be guided over a previously inserted guide wire (not illustrated) or drainage lumen 34 may contain a guide wire to increase the stiffness of the apparatus 1.

The apparatus 1 is advanced within the urethra 11 and into the prostatic urethra 9 until the dilation balloon 18 is positioned at the bladder neck 17 and in proximity with the prostate 15. Fig. 1 also shows the position of the

dilation balloon 18 relative to the pubic bone 19 and the external sphincter 21 situated in the pelvic floor. The fixation balloon 20 is, at the same time, properly located in the bulbous urethra. The doctor determines that the apparatus 1 is properly positioned by rectally palpating the protuberance 37 circumferentially located on catheter tube 12 at a position before fixation balloon 20 in a direction towards the proximal end of catheter tube 12. The position of the apparatus 1 can also be determined by fluoroscopic or ultrasonic means.

When the apparatus 1 is correctly positioned, the fixation balloon 20 is inflated with an inflation fluid circulated in fixation lumen 50. The inflation fluid fills the fixation balloon 20. The inflated fixation balloon 20 causes the apparatus 1 to be fixed such that the dilation balloon 18 and the microwave antenna 22 are in the prostatic urethra 9. For inflation of the fixation balloon 20, an inlet port on the fixation lumen 50 is connected to an inflating means, such as a syringe, and the inflation fluid is injected to inflate the fixation balloon 20 by fluid pressure.

When the inflated fixation balloon 20 is properly located at the bulbous urethra proximal to the external sphincter 21, the doctor knows that the dilation balloon 18 is at its proper location at the prostatic urethra 9 since the fixation balloon 20 of the apparatus 1 is positioned along the catheter tube 12 at a distance from the dilation balloon 18 such that when fixation balloon 20 is at the bulbous urethra, then the dilation balloon 18 is at the prostatic urethra 9. Because the apparatus 1 has such a configuration, inadvertent dilation of the external sphincter 21 and the possible harmful effects consequent therefrom are avoided.

The dilation balloon 18 is then inflated with an inflation fluid circulated through dilation lumen 38. To attain the proper inflation pressure for maximum dilation, a volume of inflation fluid is injected into dilation

balloon 18. The inflation fluid used to inflate the dilation balloon 18 can be the same as or different than the inflation fluid used to inflate the fixation balloon. Preferably, the inflation fluid used to inflate the dilation balloon 18 is deionized water, mineral oil or other suitable fluids with low dielectric properties which act to reduce refracted microwave energy and facilitate coupling of the microwave energy emitted from the surface of microwave antenna 22 into the prostatic tissue. For inflation of the dilation balloon 18, an inlet port on the dilation lumen 38 is connected to an inflating means, such as a syringe, and the inflation fluid is injected to inflate the dilation balloon 18 by fluid pressure.

In a preferred embodiment of the apparatus 1, the dilation balloon 18 is made of limited distensible material, which causes the balloon to expand upon inflation to a predetermined maximum diameter.

Expansion of dilation balloon 18 causes the dilation balloon to exert pressure against the obstructive prostatic tissue in the prostatic urethra, thereby causing a widening of the prostatic urethra to an unobstructed diameter which relieves the symptoms of BPH. The pressure exerted on the prostatic tissue also creates a reduction in blood flow to the tissue which is beneficial during the hyperthermia part of the treatment procedure when microwave energy is applied to the prostatic tissue.

The combined treatment procedure is completed, when the dilation balloon 18 has been allowed to remain expanded for an effective period of time to cause a widening of the prostatic urethra, and when an effective amount of microwave energy has been applied to the surrounding diseased prostatic tissue to cause hyperthermal effects.

Microwave antenna 22 is de-energized to terminate radiation of energy to the surrounding prostatic tissue. Dilation balloon 18 and fixation balloon 20 are then deflated by draining the inflation fluid therefrom and out

through the drainage lumens. The apparatus is then in condition for withdrawal.

CLAIMS

1. An apparatus for treatment of diseases of the prostate characterized by, in combination:

a flexible catheter tube having a distal end for insertion in the prostatic urethra, a proximal end external to the urethra from which the apparatus is manipulated and controlled, and a plurality of lumens extending the length thereof from the proximal to the distal end;

dilation means circumferentially mounted at the distal end of the catheter tube for enlarging the lumen of the prostatic urethra to relieve any constriction of the prostatic urethra generally symptomatic of most diseases of the prostate and for compressing prostatic tissue to restrict blood flow to said tissue, thereby reducing the heat sink effect caused by blood-supplied tissue absorbing heat energy applied thereto; consequently enabling both greater uniformity of heating in selected target diseased prostatic tissue and a reduction in the amount of power required to supply an effective amount of energy to said diseased tissue to produce hyperthermal effects therein; and

heating means axially mounted in the distal end of the catheter tube for applying said effective amount of energy to said selected target diseased prostatic tissue to produce said hyperthermal effects therein, thereby causing a therapeutic alteration of cells in said selected target diseased prostatic tissue.

2. The apparatus of claim 1 wherein the dilation means is an inflatable dilation balloon.

3. The apparatus of claim 1 wherein the heating means is selected from the group consisting of a microwave transmitting antenna, a radio frequency transmitting antenna, and a conductor of heat from a thermal heating fluid.

4. The apparatus of claim 1 further characterized by an inflatable fixation balloon, circumferentially attached to the catheter tube at a distance from the distal end

thereof, for correctly positioning the apparatus and maintaining it in place during use.

5. The apparatus of claim 2 wherein the dilation balloon is inflated by injection thereinto of a volume of a fluid selected from the group consisting of deionized water and mineral oil.

6. The apparatus of claim 7 wherein the fluid for inflating the dilation balloon is injected through a dilation inlet port in the catheter tube, flows into the dilation balloon through a dilation inflation lumen in the catheter tube, and is withdrawn through a dilation drainage lumen in the catheter tube to deflate the dilation balloon after dilation of the prostatic urethra and to remove the apparatus.

7. The apparatus of claim 4 wherein the fixation balloon is inflated by injection thereinto of a volume of fluid selected from the group consisting of deionized water and mineral oil.

8. The apparatus of claim 7 wherein the fluid for inflating the fixation balloon is injected through a fixation inlet port in the catheter tube, flows into the fixation balloon through a fixation inflation lumen in the catheter tube, and is withdrawn through a fixation drainage lumen in the catheter tube to deflate the fixation balloon for removal of the apparatus.

9. The apparatus of claim 6 wherein a continuous steady state flow of fluid is introduced into the dilation inlet port in addition to the amount of fluid to inflate the balloon, said steady state flow of fluid passing through the dilation inflation lumen, circulating through the inflated dilation balloon to moderate the temperature of the surface of the heating means to prevent overheating and cooling the surface of the dilation balloon which in turn cools the surface of the urethelium with which the dilation balloon is in contact to prevent hyperthermal changes to normal urethelium tissue cells, with the fluid

at an elevated temperature exiting through the dilation drainage lumen.

10. The apparatus of claim 3 wherein when the microwave transmitting antenna is selected, it is further characterized as being selected from the group consisting of a linear coaxial antenna with choke, a helical coil antenna, a single junction dipole antenna, a multiple junction dipole antenna, a sheered coaxial slot dipole antenna, a balun-fed folded dipole antenna, a bare-tip dipole antenna and an insulated-tip dipole antenna.

11. The apparatus of claim 10 wherein the energy supplied to the antenna is at a frequency of from about 50 to about 2450 MHz.

12. The apparatus of claim 2 wherein the size of the dilation balloon is from about 40 French to about 120 French in outer inflated diameter.

13. The apparatus of claim 2 wherein the heating means at the distal end of the catheter is also surrounded by the dilation balloon.

14. The apparatus of claim 1 further characterized by at least one additional element selected from the group consisting of:

a temperature sensing means mounted in a thermometry lumen of the catheter tube for sensing the temperature of the heating means;

a urine drainage lumen in the catheter tube for evacuating urine from the bladder while the apparatus is in use;

a guidewire mounted in a guidewire lumen of the catheter tube for facilitating movement of the apparatus through the urethra;

a protuberance circumferentially mounted on the catheter tube at a position along the axial length of the catheter tube which enables rectal palpation of the protuberance to facilitate correct anatomical placement of the apparatus in the urethra;

feedback circuit means for regulating the amount of energy provided to the heating means; and

a plurality of centering balloons located along the longitudinal axis of the heating element each being circumferential to the heating element, and all inside the dilation balloon, to maintain the antenna equidistant from the dilation balloon.

15. The apparatus of claim 1 wherein the heating means is detachably mounted.

16. The apparatus of claim 1 wherein the heating means is slidably mounted in the distal end of the catheter tube.

17. An apparatus for treatment of diseases of the prostate characterized by, in combination:

a flexible catheter tube having a distal end for insertion in the prostatic urethra, a proximal end external to the urethra from which the apparatus is manipulated and controlled, and a plurality of lumens extending the length thereof from the proximal to the distal end;

an inflatable dilation balloon circumferentially mounted at the distal end of the catheter tube for enlarging the lumen of the prostatic urethra to relieve any constriction of the prostatic urethra generally symptomatic of most diseases of the prostate and for compressing prostatic tissue to restrict blood flow to said tissue, thereby reducing the heat sink effect caused by blood-supplied tissue absorbing heat energy applied thereto; consequently enabling both greater uniformity of heating in selected target diseased prostatic tissue and a reduction in the amount of power required to supply an effective amount of energy to said selected target diseased prostatic tissue to produce hyperthermal effects therein;

a microwave transmitting antenna axially mounted in the distal end of the catheter tube for applying said effective amount of energy to said selected target diseased prostatic tissue to produce said hyperthermal effects

therein, thereby causing a therapeutic alteration of cells in said selected target diseased prostatic tissue.

18. An apparatus for treatment of diseases of the prostate characterized by, in combination:

a flexible catheter tube having a distal end for insertion in the prostatic urethra, a proximal end external to the urethra from which the apparatus is manipulated and controlled, and a plurality of lumens extending the length thereof from the proximal to the distal end;

an inflatable dilation balloon circumferentially mounted at the distal end of the catheter tube for enlarging the lumen of the prostatic urethra to relieve any constriction of the prostatic urethra generally symptomatic of most diseases of the prostate and for compressing prostatic tissue to restrict blood flow to said tissue, thereby reducing the heat sink effect caused by blood-supplied tissue absorbing heat energy applied thereto; consequently enabling both greater uniformity of heating in selected target diseased prostatic tissue and a reduction in the amount of power required to supply an effective amount of energy to said selected target diseased prostatic tissue to produce hyperthermal effects therein;

an inflatable fixation balloon, circumferentially attached to the catheter tube at a distance from the distal end thereof for correctly positioning the apparatus and maintaining it in place during use;

a protuberance circumferentially mounted on the catheter tube at a position along the axial length of the catheter tube between the dilation and fixation balloons to enable rectal palpation of the protuberance to facilitate correct anatomical positioning of the apparatus in the urethra;

a microwave transmitting antenna axially mounted in the distal end of the catheter tube for applying said effective amount of energy to said selected target diseased prostatic tissue to produce said hyperthermal effects

therein, thereby causing a therapeutic alteration of cells in said selected target diseased prostatic tissue;

inlet and outlet ports, at the proximal end of the catheter tube, respectively leading to and from each of the dilation and fixation balloons, with lumens interconnecting the ports and the balloons, for injecting a fluid into the balloons to inflate them, for maintaining a circulation of fluid through the dilation balloon to act as a cooling medium for cooling the surface of the microwave antenna and for cooling the surface of the dilation balloon, which in turn cools the surface of the urethelium to prevent hyperthermal effects in normal urethelium tissue cells, and for withdrawing fluid from the balloons to deflate them;

a urine drainage lumen extending the length of the catheter tube for withdrawing urine, blood and extracellular fluid; and

temperature sensing means mounted in a thermometry lumen in the catheter tube for sensing the temperature of the microwave antenna and target tissue.

19. A method for treatment of disease of the prostate comprising the steps of:

inserting into the urethra a catheter comprising a flexible tubular line having a distal and a proximal end, and containing a plurality of lumina extending the length thereof; a dilation balloon for dilating the urethral passage by compressing prostatic tissue and for restricting blood flow during catheterization; a heating element for directing energy to prostatic tissue, to produce thermal effects therein;

inflating the dilation balloon to dilate the urethral passage to relieve any constriction therein generally symptomatic of most diseases of the prostate, and to compress prostatic tissue to restrict blood flow to prostatic tissue during catheterization, thereby reducing the heat sink effect of blood-supplied tissue absorbing heat energy applied thereto; consequently enabling both greater uniformity of heating in selected target diseased

prostatic tissue and a reduction in the amount of power required to supply an effective amount of energy to said selected target diseased prostatic tissue to produce hyperthermal effects therein;

energizing the heating element to apply said effective amount of energy to said selected target diseased prostatic tissue to produce said hyperthermal effects therein, thereby causing therapeutic changes in said selected target diseased prostatic tissue;

terminating application of energy to prostatic tissue after a sufficient time to produce therapeutic results;

deflating the dilation balloon; and

withdrawing the catheter.

20. A method for treatment of disease of the prostate comprising the steps of:

inserting into the urethra a catheter comprising a flexible tubular line having a distal and a proximal end, and containing a plurality of lumina extending the length thereof; guidewire means slidably mounted in one of said lumina for directing the catheter into position; a protuberance for establishing the correct anatomical position of the catheter; a fixation balloon for holding the catheter in place when properly positioned; a dilation balloon for dilating the urethral passage and for restricting blood flow during catheterization by compressing prostatic and surrounding non-prostatic tissue; an antenna for directing microwave energy to selected target diseased prostatic tissue; cooling means for limiting the temperature rise in surrounding tissue and in the antenna during catheterization; and energy controlling means to regulate the amount of microwave energy delivered to the antenna and applied to said selected target diseased prostatic tissue, by utilizing said guidewire located in a working lumen of the tubular line to emplace the catheter in the prostatic urethra such that the antenna is positioned in proximity to the prostate;

palpating the protuberance to ensure that the catheter is positioned for catheterization;

inflating the fixation balloon to hold the catheter in position and to prevent dilation of the external sphincter;

inflating the dilation balloon to dilate the urethral passage to relieve any constriction therein generally symptomatic of most diseases of the prostate, and to compress prostatic tissue to restrict blood flow to prostatic tissue during catheterization, thereby reducing the heat sink effect of blood-supplied tissue absorbing heat energy applied thereto; consequently enabling both greater uniformity of heating in selected target diseased prostatic tissue and a reduction in the amount of power required to supply an effective amount of microwave energy to said selected target diseased prostatic tissue to produce hyperthermal effects therein;

supplying microwave energy to the antenna;

applying said effective amount of microwave energy to said selected target diseased prostatic tissue to produce said hyperthermal effects therein, thereby causing therapeutic alteration of the cells of said selected target diseased prostatic tissue;

circulating a coolant solution through the catheter and the dilation balloon to cool the urothelium and surrounding tissue; to dilate the prostatic lumen during catheterization; and to cool the surface of the antenna to enable a greater amount of the microwave energy to be applied to the target prostatic tissue and to prevent overheating of the antenna surface;

monitoring the temperature of the prostatic tissue during catheterization to ensure application of the optimum amount of microwave energy to the tissue;

controlling the amount of microwave energy applied to the prostatic tissue;

evacuating blood, urine and extracellular fluid through a drainage lumen of the tubular line;

terminating application of microwave energy to prostatic tissue after a sufficient time to produce therapeutic results;

terminating circulation of cooling fluid through the catheter;

deflating the dilation balloon;

deflating the fixation balloon; and

withdrawing the catheter.

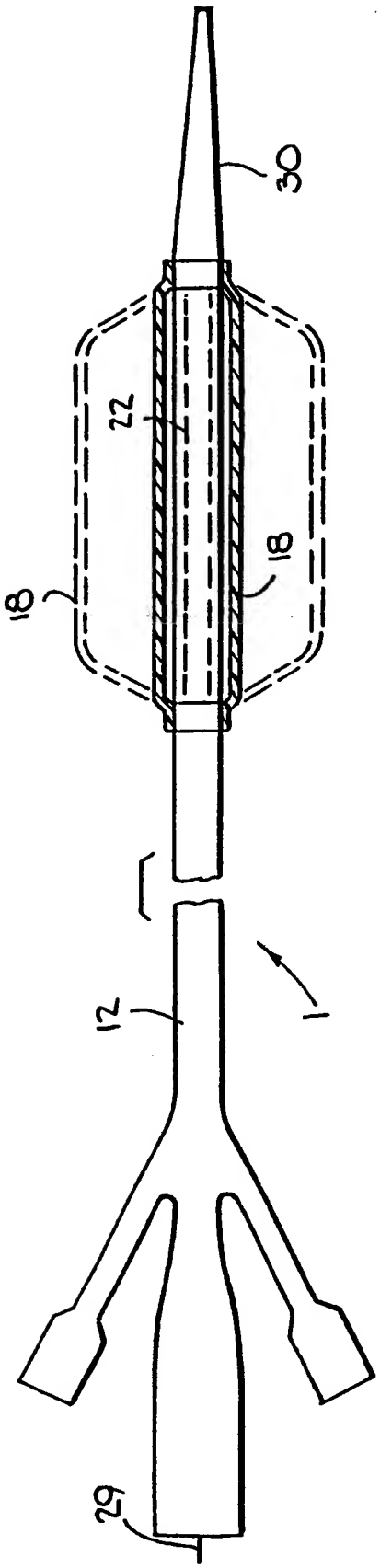
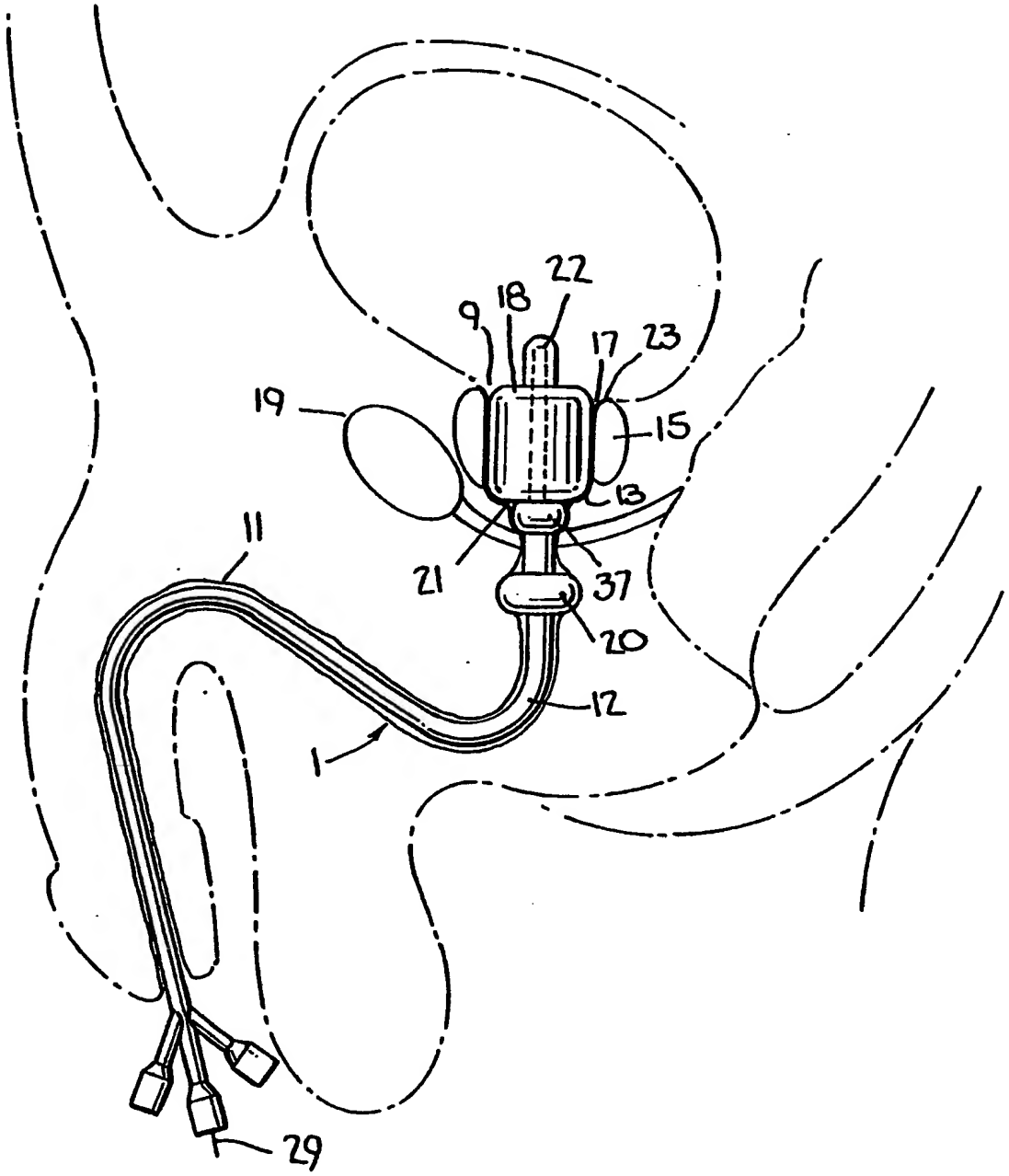


Fig. 1

Fig. 2.



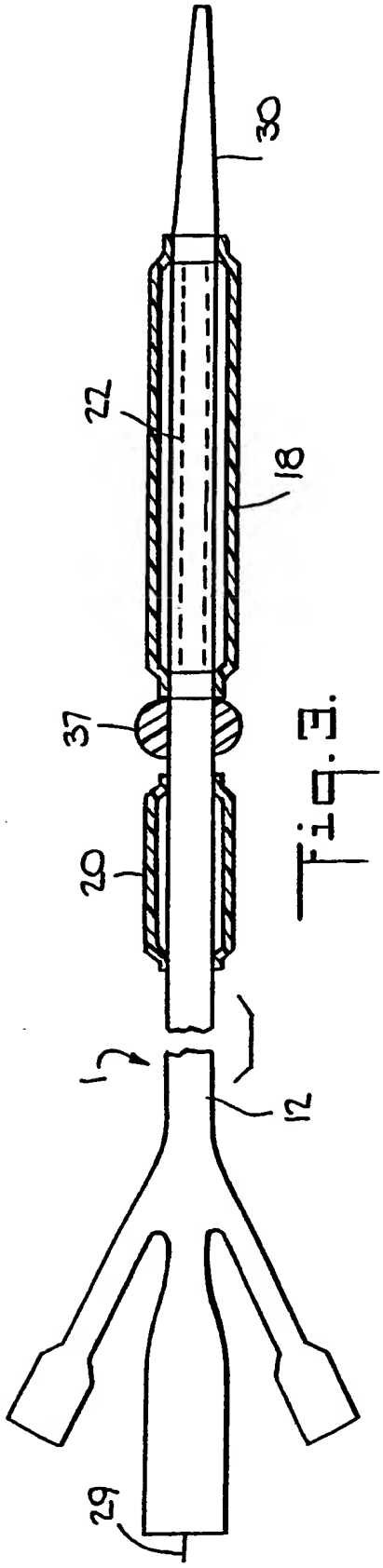


Fig. 5.

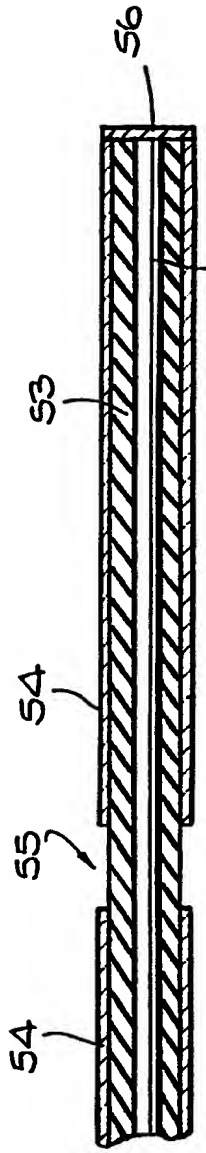


Fig. 6.

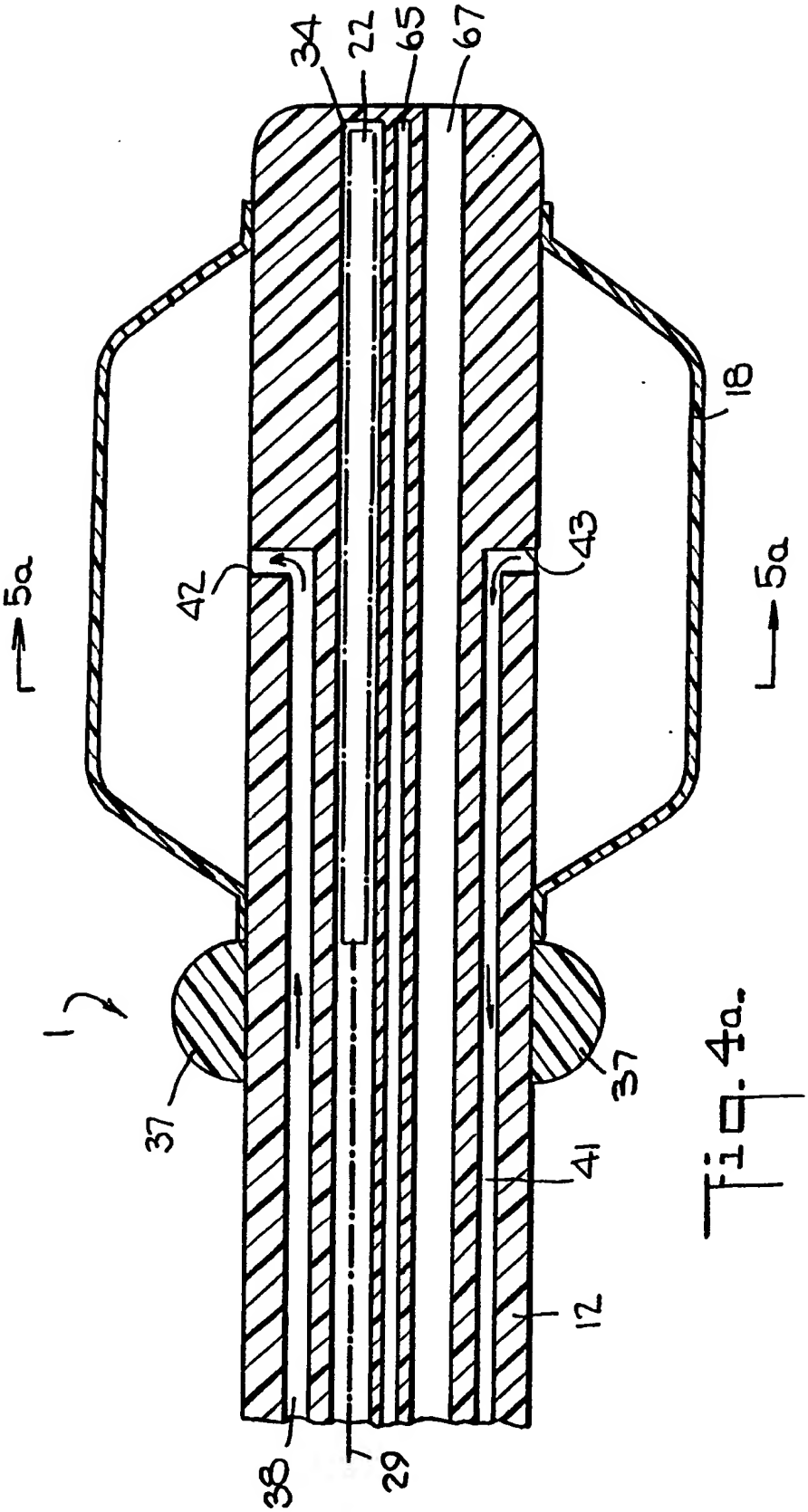


Fig. 4a.

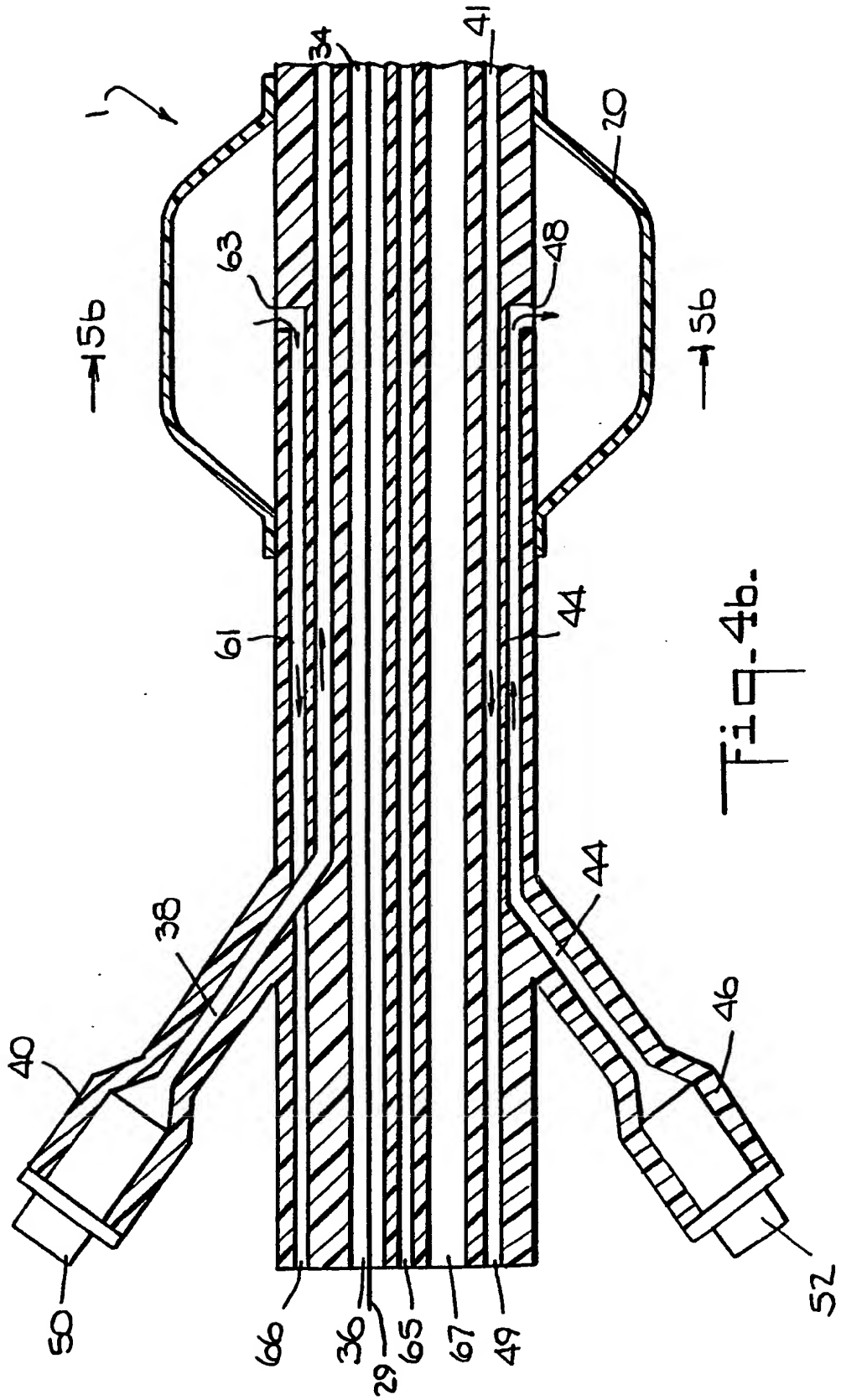


Fig. 4b.

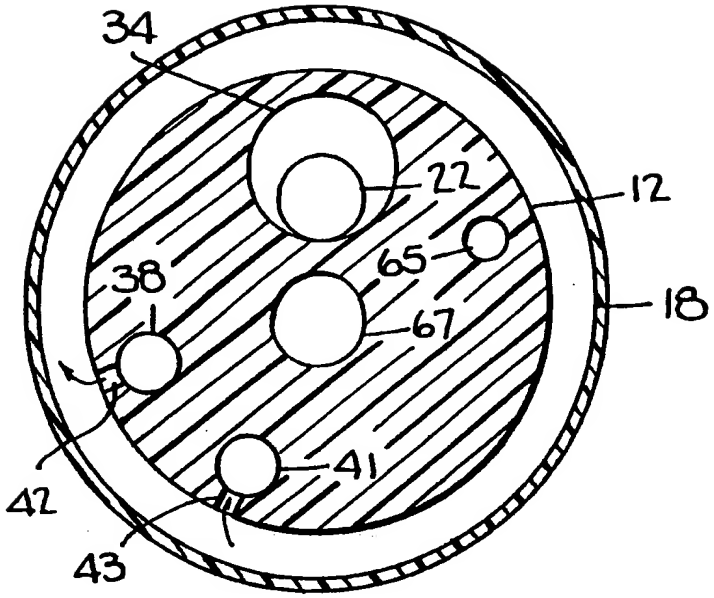


Fig. 5a.

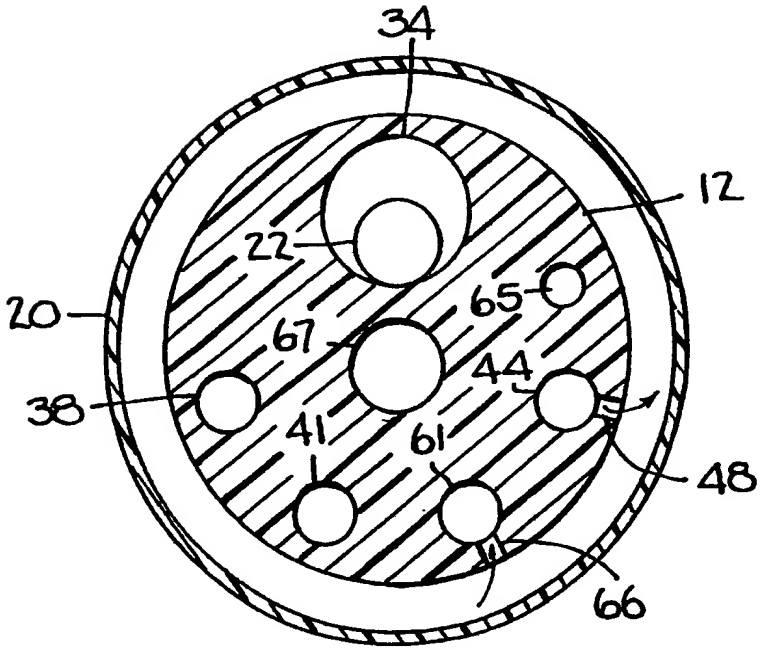


Fig. 5b.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/05173

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M29/02; A61N5/04

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M ; A61N

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X Y	EP,A,0 105 677 (KUREHA KAGAKU KOGYO) 18 April 1984 see page 8, line 8 - line 14; claims; figures	1-3,5-6, 9-14 4,7-8, 17-20
Y	EP,A,0 341 988 (AMERICAN MEDICAL SYSTEMS, INC.) 15 November 1989 cited in the application see abstract; figures & US,A,4 932 958 12 June 1990	4,7-8, 17-20
X	WO,A,8 905 609 (ZEIHER) 29 June 1989 cited in the application see abstract; claims; figures & DE,A,3 743 578 (ZEIHER) 13 July 1989	1-3, 10-14,17

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° Special categories of cited documents :[10]

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
08 NOVEMBER 1991	0[illegible] 91
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9105173 SA 50840

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/11/91
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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